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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 10/798,400 | 03/12/2004 | Nobuaki Mihara | 1029650-000147 | 6062 |
| 21839 | 7590 | 10/06/2008 | | |
| BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404 | | | EXAMINER BOUCHELLE, LAURA A | |
| | | | ART UNIT 3763 | PAPER NUMBER |
| | | | NOTIFICATION DATE 10/06/2008 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary

Application No.

10/798,400

Applicant(s)

MIHARA ET AL.

Examiner

LAURA A. BOUCHELLE

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-893)
Paper No(s)/Mail Date 7/3/08

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 6-10, 11-14, 17-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Miki et al (AU 2003/211251). Miki discloses a catheter comprising a linear wire 102, a tubular body 106 positioned on a distal end of the linear wire, the tubular body having a hollow portion and a port 107 for receiving a guidewire, the distal end of the tubular member is fixed to a proximal portion of the wire by a reinforcing tube 101, the linear wire and the tubular body are positioned so that a longitudinal axis of the linear wire does not intersect the hollow portion of the tubular member (See Figs. 1, 3). The linear wire is metal and has a covering composed of a resin material or a hydrophilic material (Page 2, paragraph 0019). The wire is controlled by an operator portion (Page 3, paragraph 0036)

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 4, 5, 15, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miki in view of Estrada et al (US 2002/0038103).

5. Claims 4, 15 differ from Miki in calling for the tubular body to include a plurality of markers. Estrada teaches a catheter having a proximal portion 11 and a distal tubular member 34 having markers 39, 45 that allow for observation of the location of the distal portion during a procedure (page 3, paragraph 0037). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Miki to include distal markers as taught by Estrada to facilitate observation of the device during a procedure.

6. Claims 5, 16 differ from Miki in calling for the tubular member to be formed of an inner layer, an outer layer, and a reinforcing member therebetween. Estrada teaches a tubular member 34 for insertion of a guidewire 36 therethrough being formed of an inner layer 43, and outer layer 44, and a reinforcing member 42 therebetween to provide the flexibility required to insert the device though the vasculature and also the stiffness to prevent kinking (page 3, paragraph 0037). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Miki so that the tubular member is made of an inner layer, an outer layer, and a reinforcing member therebetween as taught by Estrada.

7. Applicant's arguments, filed 7/3/08, with respect to the rejection(s) of claim(s) 1, 3, 6-14, 17-21 under US 20040267196 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the Australian publication of the application AU 2003211251 published in English on 9/22/03.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle
Examiner
Art Unit 3763

/L. A. B./
Examiner, Art Unit 3763